UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,832	01/25/2002	Max Costa	5986/1I147US1	1550

7278 7590 10/28/2004

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,832	COSTA ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *August 5, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-7, 10, 25-33, 35, 51, 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7, 10, 20 5-33, 35, 51, 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed August 5, 2004 in response to the Office Action of February 6, 2004 is acknowledged and has been entered. Claims 8-9, 11-24, 34, 36-50, 53-54, 57-102 have been canceled, Claims 1, 20, 25, 35, 52 and 56 have been amended. Claims 1-7, 10, 25-33, 35, 51, 55 are currently under prosecution.

2. Applicant's acknowledgement of the oral election of Group 1A drawn to an *in situ* method of identifying/diagnosing a disease cell or tissue/cancer/melanoma said disease being associated with elevated CAP43 protein expression made to the telephone restriction requirement of January 30, 2004 is noted.

3. It is noted that Applicant specifically states on page 10 of the response that "the claims as amended specify methods for identifying cancer cells or tissues (as well as individuals having such cancer cells or tissues) in which the cancer is associated with elevated CAP43 expression". It is further noted that, to the extent that the claimed *in vitro* methods identify or diagnose cancer, it would be clear that the patient from whom the cells or tissue had been taken would be identified or diagnosed as having cancer. However, it appears from this statement that Applicant is attempting to broaden the scope of the examined invention to include *in vivo* limitations. A review of the restriction requirement clearly shows that *in vivo* limitations were restricted out from the instantly examined invention and limitations other than those elected and already examined will not be examined until the linking claims are found allowable wherein any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following rejections are maintained:

Claim Rejections - 35 USC § 112

6. Claims 1-7, 10, 25-33, 35, 51, 55 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper mailed February 6, 2004, Section 13, pages 8-12.

Applicant argues that (a) unlike the insulin cDNA molecule at issue in *Eli Lilly*, at the time the application was filed, CAP43 was already well known in the art, Hence, the critical features of CAP43 protein are already well known in the art and need not be enumerated, (b) the present invention does not claim the CAP43 cDNA or any protein it includes, rather the invention specifies novel methods that detect a CAP43 gene or its gene product, (c) CAP43 protein can be detected using antibodies that specifically bind to the polypeptide and it is known in the art that such methods can be used to detect homologs and variants of gene products, even where those homologs and variants have not been previously described.

The arguments have been considered but have not been found persuasive because (a') Applicant is arguing limitations not recited in the claims as currently constituted. Contrary to Applicant's arguments, the claims are not drawn to the well known and characterized CAP43 of any of the references recited on page 3, but rather, as previously set forth, the claims are drawn to CAP43 as defined in the specification which is a gene product which comprises an amino acid sequence of one or more epitopes of a full length CAP43 wherein said epitopes preferably contain amino acids corresponding to at least 5 residues of full length CAP43 polypeptide. It is clear that the method of detecting cancer is drawn to a method of detecting a polypeptide that comprises 5 amino acids of SEQ ID NO:2 wherein neither the structure nor the function of the polypeptide to be detected is known. Further, as previously set forth, the claims are drawn to CAP43 as defined by the

specification wherein CAP43 is a gene product encoded by a nucleic acid that hybridizes, under unidentified hybridization conditions, to the complement of SEQ ID NO:1 (also undefined by the specification and taken to mean either a complete or partial complement of said nucleic acid molecule). Given this definition, it is clear that the method of detecting cancer is drawn to a method of detecting a polypeptide that is encoded by a nucleic acid which hybridizes under low hybridization conditions to a partial complement of SEQ ID NO:1 which reads on a whole universe of polypeptides with neither structure nor function related to either CAP43 or cancer. Further, the claims are drawn to a CAP43 gene product encoded by a nucleic acid with 70% identity to SEQ ID NO:1, an amino acid sequence that is at least 70% identical to SEQ ID NO:2. Given this definition, it is clear that the claims read on a whole universe of polypeptides wherein no functional characteristics, if the thus defined, (b') although neither the CAP43 cDNA or protein are claimed, a disclosure that does not adequately describe a product critical to the claimed method cannot adequately described a method of using that product, (c') the rejection is not drawn to conventional antibody assays, rather the rejection is drawn to the lack of written description of the invention as claimed. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

7. Claims 1-7, 25-33, 51, 55 remain rejected under 35 USC 102(e) for the reasons previously set forth in Paper mailed February 6, 2004, Section 18, pages 14-17.

Applicant argues that Adams merely teaches that expression of the gene he refers to as RTP/DRG/Ndrl is increased under hypoxic conditions and reports that

RTP/DRG/NDR expression is elevated in cells when grown under hypoxic conditions. Adams reports that cells grown under normal conditions do not stain for RTP/DRG/Ndr1 expression and thus Adams teaches that RTP/DRG/Ndr1 is only expressed in certain cells when cultured under particular conditions and Adams teaches that expression of RTP/DRG/Ndrl is not upregulated in cancer cells cultured under normal/nonhypoxic conditions and thus actually teaches away from the presently claimed invention.

The arguments have been considered but have not been found persuasive because, as previously set forth, Adams specifically teaches that Drg1 is unregulated in hypoxic conditions that occur in neoplastic cells *in vivo* and that the invention can be used for diagnosis for diseases and conditions in which the vasculature of the affected tissue is altered so that blood flow is reduced and the tissue is rendered hypoxic and Adams specifically states that the diagnostic methods of the patented invention include the diagnosis of cancer. Further, it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo* and the demonstration that cancer cells in culture under normal/nonhypoxic conditions do not overexpress Drg1 is clearly a demonstration of those differences. The relevant issue here is not that cultured cancer cells under normal/nonhypoxic conditions, wherein Adams teaches that the *in vivo* environment of these cells is hypoxic, do not overexpress Drg1, but rather that Adams specifically teaches that hypoxic conditions occur in *in vivo* in if neoplastic cells and that Adams specifically teaches that the diagnostic methods of the patented invention include the diagnosis of cancer. The arguments have been considered but have not been found persuasive and the rejection is maintained.

8. Claims 1-7, 10, 25-33, 35, 51, 55 remain rejected under 35 USC 102(f) for the reasons previously set forth in Paper mailed February 6, 2004, Section 19, pages 17-18.

Applicant states that Dr. Cangul's contributions to the work leading to the invention claimed in this application are currently being investigated. Applicants agree that the application will be amended to include the name of Dr. Cangul as co-inventor if appropriate.

The rejection is maintained for the reasons of record.

9. All other objections and rejections imposed in the Paper mailed February 6, 2004 are hereby withdrawn.

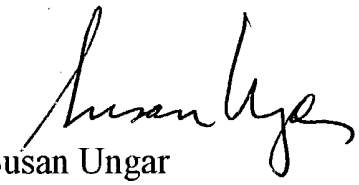
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Susan Ungar
Primary Patent Examiner
October 20, 2004